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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

03/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/569,012

Applicant(s)

DE LAS HERRERIAS ET AL.

Examiner

Marianne P. Allen

Art Unit

1647

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 18, 19, 26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 18, 30, 32-34 is/are rejected.
- 7) ☒ Claim(s) 2, 19, 26, 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office action supersedes the Office action mailed on 2/19/2009. The previously mailed action inadvertently reproduced the prior Office action mailed 7/31/2008 rather than the final Office action set forth below. The examiner apologizes for any confusion.

Applicant's arguments filed 12/1/2008 have been fully considered but they are not persuasive.

Claims 10-17, 20-25, and 27 have been cancelled. Claims 28-34 have been newly added. Claims 1-9, 18-19, 26, and 28-34 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-9, 18, 30, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 1 as amended recites, "A peptide comprising an amino acid sequence selected from SEQ ID NO: 17, or between 9 and 14 consecutive amino acid residues of SEQ ID NO: 17,

and their pharmaceutically acceptable salts, wherein the peptide is characterized by a capacity to bind to transforming growth factor $\beta 1$ (TGF- $\beta 1$)."

Basis for "between 9 and 14 consecutive amino acid residues" has been pointed to on page 7, lines 4-11. This is not agreed with. This is a description of the particular sequences recited in claim 2 that meet these size limitations. It is not a disclosure of any 9-14 amino acid fragment of SEQ ID NO: 17.

Claim 9 has been amended to recite "one or more alternative." Basis is not seen for this generic concept in original claim 6. The specification does not appear to contemplate such compositions.

Claim 33 is a new claim and basis has been pointed to at page 6. This is not agreed with. The specification does not contemplate this subset of consecutive amino acid residues of SEQ ID NO: 17.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable producing any pharmaceutical compositions for the treatment of diseases and pathological alterations associated with excessive or deregulated expression of TGF- $\beta 1$. The specification provides no evidence or reason to believe that any of the peptides embraced by claim 1 is useful for the treatment of any of the diseases embraced by these claims. The specification does not administer any peptides in vivo or in an in vitro model

that corresponds to any of these diseases. As these are not naturally occurring peptides, it is not considered to be so predictable that they would have any in vivo activity suitable to treat these diseases.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 17 and SEQ ID NOS: 24-36, does not reasonably provide enablement for all fragments embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable other peptide fragments of SEQ ID NO: 17 embraced by the claims as having the capacity to bind to transforming growth factor $\beta 1$ (TGF- $\beta 1$). Table 4 in the specification shows that a 9 amino acid fragment (the smallest fragment tested) has barely any activity. There is no reason to believe that smaller peptides would bind or have any activity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 7, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is directed to methods of making a pharmaceutical composition. Claims 5-7 do not provide further limitations to the steps for making the pharmaceutical composition (i.e. introducing the peptide of claim 1 into a pharmaceutically acceptable excipient). They do not

further limit the peptide or carrier required by the pharmaceutical composition. Claims 5-7 do not further limit the subject matter of claim 4. Applicant's arguments are not persuasive.

Applicant has not pointed out how the pharmaceutical composition produced by the method of claim 4 is further defined by the limitations in claims 5-7. None of these claims alter any of the structural features of the pharmaceutical compositions produced by the method of claim 4. As such, it must be presumed that all of the pharmaceutical compositions produced by claim 4 would fulfill all of the intended uses of claims 5-7.

Claim 8 recites "in therapeutically effective amount." However, the intended therapeutic effect is not specified. The claim is indefinite on the amount of peptide required by the claim.

Claim 9 recites "alternative TGF- β 1 inhibiting compounds." It is not known what is meant by "alternative."

Conclusion

SEQ ID NO: 17 is a synthetic peptide and is not naturally occurring. SEQ ID NOS: 24-36 are different truncated forms of SEQ ID NO: 17. The prior art of record does not disclose nor suggest the structure of any of these peptides.

Claims 2, 19, 26, and 28-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 31 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa